08-11-00 A1

U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION TRANSMITTAL LETTER	ATTORNEY DOCKET NO.: 2565/76

Address to:
Assistant Commissioner for Patents
Washington D.C. 20231
Box Patent Application

Transmitted herewith for filing is the patent application of

Inventor(s) **Wolfgang BIESEL**

For : **DEVICE AND METHOD FOR AUTOLOGOUS BLOOD TRANSFUSION**

1. **6** sheets of specification, **3** sheets of claims, and **1** sheet of abstract.
2. **1** sheet(s) of drawings.
3. Declaration (unsigned).
4. A certified copy of German Patent Application No. 199 38 287.5 filed August 12, 1999, on which the claim to priority is based.
5. Information Disclosure Statement and PTO 1449 with references.

Express Mail No. EL3027003214US

6. The filing fee has been calculated as shown below:

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BASIC FEE				690.00
TOTAL CLAIMS	10 - 20 =	0	18.00	0.00
INDEPENDENT CLAIMS	3 - 3 =	0	78.00	0.00
MULTIPLE DEPENDENT CLAIM PRESENT			260.00	0.00
*Number extra must be zero or larger			TOTAL	690.00
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7. Please charge the required application filing fee of **$690.00** to the deposit account of **Kenyon & Kenyon**, deposit account number **11-0600**.

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9. A duplicate of this sheet is enclosed.

Dated: August 10, 2000 By: _____

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DEVICE AND METHOD FOR AUTOLOGOUS BLOOD TRANSFUSION

Field of the Invention

The present invention relates to a device for autologous blood transfusion having a centrifuge unit with an autotransfusion set mounted thereto. The present invention also relates to a method of autologous blood transfusion.

Background of the Invention

There are various known devices and methods of obtaining concentrates from certain blood components. To obtain a platelet concentrate, for example, blood from a donor in an extracorporeal circulation is centrifuged and separated into its components. An example of a device for carrying out such a method is disclosed in German Patent Application No. 42 27 695.

Platelet concentrates are needed for treating thrombocytopenic patients. Although it is generally sufficient to separate leukocytes by centrifugation, leukocytes, which are capable of causing an immune response, are preferably eliminated in transfusions of foreign blood to prevent undesirable immune system reactions in a patient.

In addition to transfusion of foreign blood, there has been widespread use of intraoperative autotransfusion, where the patient's own blood is collected during the surgery and retransfused back into the patient. The advantage of transfusion of autologous blood is that it prevents the transmission of infectious diseases such as AIDS and hepatitis

while also avoiding transfusion reactions due to biological incompatibility and immune system reactions. So-called whole blood transfusion methods, where the collected blood is merely subjected to particle filtration, and plasma separation/washing methods, which supply washed erythrocyte concentrates for reinfusion, are used in the field of intraoperative autotransfusion. An example of a known autologous blood transfusion device is described in International Patent Application No. WO 99/02269.

In transfusion of foreign blood, there is the risk of immune reactions, but immune reactions do not occur with autotransfusion (autologous blood transfusion). On the other hand, the possibility of physiological reactions cannot be ruled out because the leukocytes are traumatized and/or activated in collection. It has been found that tumor cells, which may result from the autologous blood transfusion, may be eliminated by leukocyte depletion filters. U.S. Patent No. 5,744,047 describes a leukocyte filter which is also used for autologous blood transfusions.

Summary of the Invention

The object of the present invention is to create a device for autologous transfusion of blood with a centrifuge unit having an autotransfusion set rotatably mounted thereto and an autotransfusion set for such a device so that the safety of autologous transfusion is further increased.

Another object of the invention is to provide an improved method of autologous blood transfusion.

To prevent physiological reactions due to activated or traumatized leukocytes or metastases due to tumor cells, a

filter for eliminating leukocytes and/or tumor cells that may cause immune reactions or metastases is integrated into the autotransfusion set. Leukocytes and/or tumor cells are eliminated with the known leukocyte depletion filters which can also bind specific tumor cells in addition to leukocytes. In addition, particulate impurities are eliminated by the leukocyte depletion filters.

Leukocytes and/or tumor cells can be eliminated in principle before or after processing the blood. However, eliminating the leukocytes before processing reduces the quantity of products of leukocyte activation or traumatization of the blood product for transfusion. Therefore, the filter for elimination of leukocytes and/or tumor cells is preferably arranged in the blood supply line leading to the separation unit of the autotransfusion set.

Known autotransfusion sets generally have a collecting tank, also known as a cardio reservoir, arranged in the blood supply line. The filter for eliminating leukocytes and/or tumor cells is preferably arranged in the collecting tank. This is advantageous inasmuch as no separate filter housing is needed. Providing the leukocyte depletion filter in the collecting tank not only eliminates the need to provide a separate filter housing but also prevents the risk of leakage due to additional connecting parts. The filter for eliminating leukocytes and/or tumor cells may be arranged in the collecting tank together with the filter which is preferably generally provided with the known cardio reservoir to remove particulate impurities. To this extent, the manufacturing cost is low.

If the autologous blood is filtered before being

collected in the tank, a rapid reinfusion is possible if necessary. However, placing the filter in the blood supply line leading to the patient limits the flow of the cell fraction to be retransfused back into the patient. The filter for eliminating leukocytes and/or tumor cells should have the largest possible filter surface area so that large volumes of blood can be freed of leukocytes and/or tumor cells in a short period of time.

Brief Description of the Drawings

FIG. 1 shows a schematic diagram of the device for autologous blood transfusion together with the autotransfusion set according to the present invention.

Detailed Description

FIG. 1 illustrates the components of a device for autologous transfusion of blood together with the autotransfusion set in a simplified diagram. The autotransfusion set, which is designed as a disposable set, is inserted into the device for autologous transfusion. The autotransfusion set 1 comprises a separation unit 2 for concentrating a cell fraction and a tubing system 3 for providing a connection to a patient.

Separation unit 2 is a centrifuge chamber with an annular channel 4 having an inlet 5 for the blood to be processed and an outlet 6 for the concentrated cell fraction, e.g., an erythrocyte concentrate. Such a centrifuge chamber is described in detail in German Patent No. 42 26 974, for example, which is incorporated herein by reference.

The tubing system 3 of the autotransfusion set comprises a blood supply line 7 for supplying blood removed from the patient, and a blood return line 8 for retransfusion of the blood processed in the separation unit 2.

Blood supply line 7 leads to the inlet 11 of a collecting tank 12 for the collected, anticoagulant-treated blood. A second section 14 of the blood supply line 7 leads from the outlet 13 of collecting tank 12 to the inlet 5 of separation channel 4. The blood return line 8 is connected to the outlet 6 of channel 4 and has at the end a connection 15 to a transfer bag (not shown). The collecting tank 12 is connected to a device 16 for generating a vacuum to draw the blood in. A filter insert 17 inserted into collecting tank 12 has a filter 20 dividing the collecting tank into two chambers to eliminate leukocytes and/or tumor cells. A connection 10 is provided for supplying an anticoagulant.

The device for autologous transfusion of blood has a centrifuge unit 21. The separation unit 2 of the autotransfusion set 1 is positioned in the device for autologous transfusion to provide for the rotation of the separation unit. The patient's blood to be processed flows through the first section 9 of the blood supply line 7 into the first chamber 18 and through filter 20 into the second chamber 19 of the collecting tank 12, where leukocytes and/or tumor cells are retained. Blood from which the leukocytes and/or tumor cells have been removed then flows out of collecting tank 12, through the second section 14 of the blood supply line 7 into the rotating separation unit 2, where a cell fraction such as the erythrocyte fraction is concentrated. The erythrocyte concentrate is then sent to the transfer bag (not shown) through the blood return line 8 for

temporary storage and is reinfused back into the patient.

The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof and accordingly reference should be made to the appended claims rather than the foregoing specification as indicating the scope of the invention.

What is claimed is:

1. A device for autologous blood transfusion comprising:

an autotransfusion set including a separation unit for concentrating a cell fraction, a tubing system for providing a connection to a blood supply, and a filter means for eliminating at least one of leukocytes and tumor cells, the tubing system including a blood supply line leading to the separation unit for supplying blood to be processed, and a return line leading away from the separation unit for supplying the concentrated cell fraction; and

a centrifuge unit, the separation unit of the autotransfusion set being rotatably mounted to the centrifuge unit.

2. The device of claim 1, wherein the filter means is arranged in the blood supply line of the tubing system.

3. The device of claim 2, wherein the autotransfusion set includes a blood collecting tank having an inlet and an outlet, the blood supply line includes a first section connected to the inlet of the collecting tank and a second section connected to the outlet of the collecting tank, and the filter means is arranged in the collecting tank.

4. The device of claim 3 further including means for supplying an anti-coagulant, the means for supplying an anti-coagulant being connected to the blood supply line of the tubing system.

5. An autotransfusion set for a device for autologous blood transfusion comprising:

a separation unit for concentrating a cell fraction;

a tubing system including a blood supply line leading to the separation unit for supplying blood to be processed, and a blood return line leading away from the separation unit for supplying the concentrated cell fraction, and

filter means for eliminating at least one of leukocytes and tumor cells.

6. The autotransfusion set of claim 5, wherein the filter means is arranged in the blood supply line of the separation unit.

7. The autotransfusion set of claim 6, wherein the tubing system includes a blood collecting tank having an inlet and an outlet, the blood supply line includes a first section connected to the inlet of the collecting tank and a second section connected to the outlet of the collecting tank, and the filter means is arranged in the collecting tank.

8. The autotransfusion set of claim 7 further including means for supplying an anti-coagulant, the means for supplying an anti-coagulant being connected to the blood supply line of the tubing system.

9. A method of autologous blood transfusion comprising the steps of:

collecting a quantity of blood from a patient;

passing the blood through a filter to eliminate at least one of leukocytes and tumor cells;

centrifuging the filtered blood in order to concentrate a cell fraction, and

returning the concentrated cell fraction to the patient.

10. The method of claim 9 wherein the quantity of blood is treated with an anti-coagulant.

Abstract

A device for autologous blood transfusion includes a centrifuge unit with an autotransfusion set rotatably mounted thereto. The autotransfusion set includes a separation unit for concentrating a cell fraction by centrifugation and a tubing system for providing a connection to a blood supply. The tubing system includes a blood supply line leading to the separation unit for supplying blood to be processed and a return line leading away from the separation unit. A filter is integrated into the autotransfusion set in order to eliminate leukocytes and/or tumor cells, thereby yielding greater safety in autotransfusion.

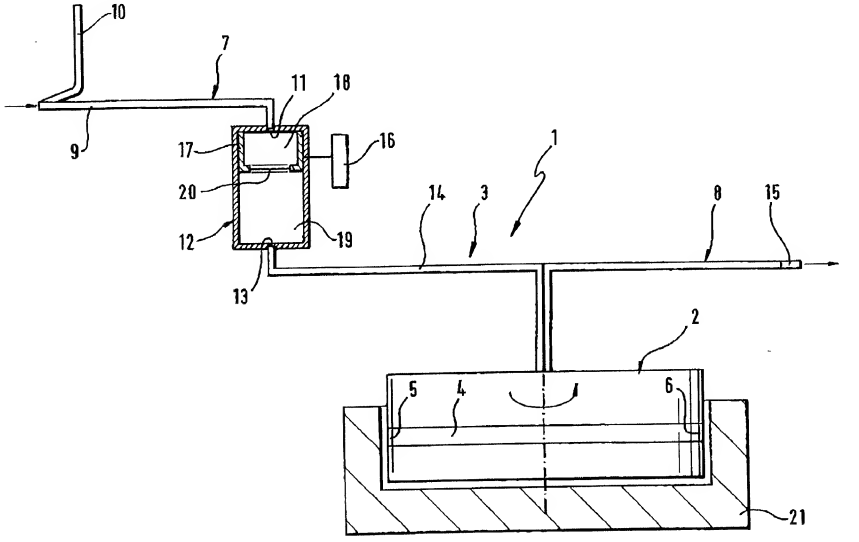

Fig. 1

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DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original and first and joint inventor of the subject matter that is claimed and for which a patent is sought on the invention entitled **DEVICE AND METHOD FOR AUTOLOGOUS BLOOD TRANSFUSION**, the specification of which is attached herewith.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.

I acknowledge the duty to disclose information that is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

(Number)	(Country)	(Day/month/year filed)	Yes X No ___ Priority Claimed Under 35 USC 119
199 38 287.5	Germany	12 August 1999	

And I hereby appoint Richard L. Mayer (Registration No. 22,490), Thomas J. Meloro (Registration No. 33,538) and Jeffrey S. Ginsberg (Registration No. 36,148) my attorney with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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